



Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment¹

This standard is issued under the fixed designation F2503; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ϵ) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This international standard applies to the practice of marking of items that might be used in the magnetic resonance (MR) environment.

1.2 The purpose of this practice is to mark items that might be brought into the MR environment and to recommend information that should be included in the marking.

1.3 The standard specifies the permanent marking of items, which are used in an MR environment, by means of terms and icons.

1.4 MR image artifacts are not considered to be a performance issue and so are not addressed in this international standard practice (see **X1.5**).

1.5 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.6 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

2.2 ASTM Standards:²

F2052 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the

Magnetic Resonance Environment

F2119 Test Method for Evaluation of MR Image Artifacts from Passive Implants

F2182 Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging

F2213 Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment

2.3 Other Standards:

IEC 60601-2-33 Medical Electrical Equipment—Part 2-33: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis³

ISO 14971 Medical Devices—Application of Risk Management to Medical Devices⁴

ISO/IEC Guide 51 Safety Aspects—Guidelines for their Inclusion in Standards⁴

ISO TS 10974 Assessment of the Safety of Magnetic Resonance Imaging for Patients with an Active Implantable Medical Device⁴

3. Terminology

3.1 Definitions:

3.1.1 *harmful interaction*—unintended direct or indirect interaction of items with MR equipment, especially with the static magnetic field, the gradient fields and the RF fields of the MR equipment, that can pose hazards to patients or other persons.

NOTE 1—In this context, the affected image quality or image artifacts are not considered to be a harmful interaction.

3.1.2 *hazard*—potential source of harm. **ISO/IEC Guide 51**

3.1.3 *item*—object that might be brought into the MR environment.

3.1.4 *magnetically induced displacement force*—force produced when a magnetic object is exposed to the spatial gradient

¹ This practice is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.15 on Material Test Methods.

Current edition approved June 1, 2013. Published July 2013. Originally approved in 2005. Last previous edition approved in 2008 as F2503–08. DOI: 10.1520/F2503-13.

² For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

³ Available from International Electrotechnical Commission (IEC), 3, rue de Varembe, P.O. Box 131, CH-1211 Geneva 20, Switzerland, <http://www.iec.ch>.

⁴ Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, <http://www.ansi.org>.